DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. 2004N–0461]

Environmental Assessment; Categorical Exclusions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulation on environmental impact considerations to expand existing categorical exclusions to include approvals of humanitarian device exemptions (HDEs) and establishment of special controls as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an environmental assessment (EA) nor environmental impact statement (EIS) is required. Regulations issued by the Council on Environmental Quality require that all Federal Agencies assess the environmental impact of their major actions and ensure that the interested and affected public is informed of environmental analyses. FDA is taking this action in accordance with the National Environmental Policy Act (NEPA).

DATES: Submit written or electronic comments on the proposed rule by [*insert date 30 days after date of publication in the* **Federal Register**]. FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

ADDRESSES: You may submit comments, identified by 2004N–0461, by any of the following methods:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

• Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

• E-mail: *fdadockets@oc.fda.gov*. Include [Docket No. 2004N–0461] in the subject line of your e-mail message.

• FAX: 301-827-6870.

• Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No(s). or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–2970.

SUPPLEMENTARY INFORMATION:

I. National Environmental Policy Act

NEPA requires all Federal Agencies to assess the environmental impact of major actions and to ensure that the interested and affected public is informed of environmental analyses. The Council on Environmental Quality (CEQ) is responsible for overseeing Federal efforts to comply with NEPA. Both CEQ and FDA have issued regulations governing agency obligations and responsibilities under NEPA. In the **Federal Register** of March 15, 1973 (38 FR 7001), FDA issued its first regulations to implement NEPA. FDA amended these regulations in the **Federal Register** of April 15, 1977 (42 FR 19986), based on consideration of revised guidelines for preparing EISs issued by CEQ. In 1978, CEQ replaced its guidelines with regulations implementing the procedural requirements of NEPA (40 CFR parts 1500 to 1508). To comply with CEQ regulations, in the **Federal Register** of April 26, 1985 (50 FR 16636), FDA revised its NEPA policies and procedures (part 25 (21 CFR part 25)).

The CEQ regulations, which are binding on all Federal executive agencies, establish procedures for implementing NEPA. Agencies may adopt procedures to supplement CEQ's regulations. In adopting NEPA-implementing procedures, Federal Agencies are directed by CEQ to reduce paperwork (40 CFR 1500.4(p) and 1500.2(b)) by using several means, including the use of categorical exclusions. Under the CEQ regulations, agencies are required to review their policies and procedures and, in consultation with CEQ, revise them as necessary to ensure full compliance with the purpose and provisions of NEPA (40 CFR 1507.3).

CEQ defines categorical exclusions as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor an EIS is required (40 CFR

1508.4). When categorically excluding an action, an agency must determine that there are no extraordinary circumstances related to the action that may result in the action having significant environmental effects.

In the **Federal Register** of July 29, 1997 (62 FR 40570), FDA published final regulations governing compliance with NEPA as implemented by the CEQ regulations. The final rule listed certain device actions as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor an EIS is required.

II. Special Controls

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq*.), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115), and the Medical Device User Fee and Modernization Act (Public Law 107–250) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three classes of devices that receive varying levels of regulation, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. Class II devices are those for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, post market surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

Prior to SMDA, the statutory definition of class II contemplated only the establishment of mandatory performance standards under section 514 of the act (21 U.S.C. 360d). The SMDA, however, broadened the definition of a class II device to provide options in addition to the establishment of a performance standard. Consistent with the pre-SMDA definition of a class II device, FDA had categorically excluded issuance, amendment, or repeal of a standard for a class II device (§ 25.34(c)). Because the agency may now establish special controls that include options in addition to mandatory performance standards, FDA is proposing to amend its environmental impact regulation under § 25.34 to expand the existing categorical exclusions. FDA proposes to include issue, amendment, or repeal of a rule related to the establishment of any special control, if it will not result in an increase in the existing levels of use or changes in the intended use of a device or its substitutes.

Generally, FDA issues special controls in order to assure that class II devices provide a reasonable assurance of safety and effectiveness. The categorical exclusion does not apply if the action will result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes. Under these conditions, FDA believes that it is appropriate to categorically exclude the establishment of a special control from the requirement to prepare an EA or EIS.

III. Humanitarian Device Exemption

The SMDA added section 520(m) to the act (21 U.S.C. 360j(m)) to encourage the development of devices intended for use in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals in the United States (humanitarian use devices). Accordingly, section 520(m) of the act authorizes FDA to exempt humanitarian

use devices from the ''effectiveness requirements'' of sections 514 and 515 of the act (21 U.S.C. 360e) (i.e., ''reasonable assurance that the device is effective''). FDA may grant such an exemption provided that the following occurs: (1) The device is designed to treat or diagnose a disease or condition that affects fewer that 4,000 individuals in the United States; (2) the device would not be available to a person with such disease or condition unless the exemption is granted; (3) no comparable device (other than the device that has been granted such an exemption) is available to treat or diagnose the disease or condition; and (4) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risk and benefits of currently available devices or alternative forms of treatment.

There are two steps to obtaining approval of a humanitarian use device. First, the applicant must submit a request for humanitarian use device designation to FDA's Office of Orphan Products Development (§ 814.100(c)(1) (21 CFR 814.100(c)(1))). Next, the applicant must submit an HDE application (§ 814.100(c)(2)). Approval of an HDE authorizes marketing of the device. Designation of a device as a humanitarian use device is not a ''major federal action'' subject to analysis under NEPA because it is a determination that a device is eligible to apply for HDE approval and is not a final determination that any particular device may be marketed. A determination that a device is eligible to apply for HDE approval cannot by itself affect the environment. (*See Alliance for Bio-Integrity* v. *Shalala*, 116 F. Supp. 2d 166, 174 (D.D.C. 2000)).

FDA is proposing to amend § 25.34 to include approval of an HDE as a category of action that does not individually or cumulatively have a significant

effect on the human environment and for which neither an EA nor EIS is required. Because humanitarian use devices are limited by definition to use for treating or diagnosing diseases or conditions affecting fewer than 4,000 individuals in the United States per year, any environmental impact associated with use of a humanitarian use device is very limited. Additionally, FDA approves few HDEs (34 over the 7 years the program has been in effect), further limiting any potential environmental impact. Finally, FDA's experience in reviewing HDEs has shown that no HDE reviewed thus far has had a significant environmental impact.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an EIS is required.

V. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule provides for an exclusion from the requirement to

prepare an EA or EIS and, as such, relieves a burden, the agency certifies that the proposed rule will not have significant impact on substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $110 million. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Paperwork Reduction Act of 1995

This proposed rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

List of Subjects

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of the Food and Drug Administration, it is proposed that 21 CFR part 25 be amended as follows:

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

1. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

2. Section 25.34 is amended by revising paragraph (b) and adding paragraph (i) to read as follows:

§ 25.34 Devices and electronic products.

* * * * *

(b) Classification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.

* * * * *

(i) Approval of a humanitarian device exemption under subchapter H of part 814 of this chapter.

Dated: November 8, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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